REMARKS

Claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29 and 31-33 are all the claims pending in the application. Claims 1, 5, 18, 21 and 33 have been amended to delete "phosphatidylinositol" and claims 7 and 23 have been amended to delete "distearoylphosphatidylinositol" and "dioleoylphosphatidylinositol".

Entry of the above amendments is respectfully requested.

I. Response to Rejection of Claims 1-5, 9, 13, 15, 16, 18-21, 29, and 31

Claims 1-5, 9, 13, 15, 16, 18-21, 29, and 31 are rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Yamada et al. (publication, June 26, 2002; JP '562), as evidenced by M. Schneider (Chapter Seven Fractionation and purification of Lecithin. Lechithins: Sources, Manufacture & Uses; Edited by Szuhaj 1988).

Applicants respectfully traverse the rejection.

Basically, the Examiner cites Yamada et al. as disclosing in paragraph [0017] a fat emulsion preparation comprising lidocaine, propofol, soybean oils and yolk lecithin. Further, the Examiner asserts that yolk lecithin includes the stabilizer of claim 1, as evidenced by M. Schneider.

Claim 1 relates to a fat emulsion with which a local anaesthetic is mixed before use, and which comprises propofol, an oily component, and an emulsifier, the fat emulsion further comprising a stabilizer selected from the following (a), (b), (c), or (d). Component (a) is at least one phospholipid selected from the group consisting of phosphatidylglycerol, phosphatidic acid, and phosphatidylserine wherein a fatty acid esterified to a glycerol moiety is a C_{18-22} linear or branched, saturated or unsaturated fatty acid.

M. Schneider does not disclose phosphatidylglycerol, phosphatidic acid or phosphatidylserine as a component of egg lecithin at page 112, Table 7-2.

Regarding phosphatidylethanolamines among the components indicated by the Examiner as being contained in yolk lecithin, claim 1 recites that component (b) is "at least one phospholipid derivative selected from phosphatidylethanolamines modified with polyalkyleneglycol, wherein a fatty acid esterified to a glycerol moiety is a C_{10-22} linear or branched, saturated or unsaturated fatty acid." That is, as a stabilizer (b), claim 1 recites phosphatidylethanolamines modified with polyalkyleneglycol.

In Table 7-2, on page 112 of M. Schneider, phosphatidylethanolamine is included as a component of egg lecithin, but phosphatidylethanolamines modified with polyalkyleneglycol are not disclosed. Consequently, the yolk lecithin disclosed in Yamada et al. does not include phosphatidylethanolamines modified with polyalkyleneglycol, and is not a stabilizer (b) as required in claim 1.

Further, Table 7-3, on page 112, in M. Schneider, shows various saturated and unsaturated fatty acids under the title "Fatty Acid Compositions." However, these fatty acids are described as in fatty acid breakdown, and are shown in terms of the fatty acid amount when decomposed from lecithin.

In egg lecithin, fatty acids are not present as free fatty acids decomposed from lecithin, but are bound to the glycerol backbone of phospholipids. This is evident from the description on page 112, lines 11 to 13, in M. Schneider where it is stated that "unsaturated fatty acids are predominantly bound to the two-position of the glycerol backbone of both triglycerides and phospholipids." In this regard, the fact that fatty acid residues are bound to the main chain of phosphatidylcholine by ester linkage is clearly shown in the chemical structure in PDRhealth cited in the previous Office Action.

As described above, the fatty acids in egg lecithin are in a form bound to phospholipids and are not free fatty acids separated from the phospholipids. For this reason, the yolk lecithin

disclosed in Yamada et al. does not include saturated or unsaturated fatty acids, i.e., stabilizer (c), as recited in claim 1.

Furthermore, as explained above, the present invention requires a specific stabilizer (a), (b), (c) or (d). The use of such a specific stabilizer enables a fat emulsion to be free of an affected emulsion stability even when a local anaesthetic such as lidocaine is admixed.

Yamada et al. merely teaches the use of a hydrophilic surfactant having 10 or more HLB as a stabilizer. Further, as mentioned above, the yolk lecithin mixed in a fat emulsion disclosed in Yamada et al. is clearly different in structure from the stabilizers used in the present invention.

For at least the foregoing reasons, Yamada et al. does not disclose the claimed fat emulsion containing a stabilizer (a), (b), (c) or (d), as recited in claim 1.

Hence, Yamada et al. does not anticipate claim 1 or claims 2-5, 9, 13 and 15, which depend from claim 1, for at least the same reasons as claim 1.

With respect to claims 18-21, 29 and 31, these claims relate to a pain-relieving fat emulsion further comprising a local anesthetic. These pain-relieving fat emulsions comprise a stabilizer (a), (b) (c) or (d), which are recited in claim 1. Given this, claims 18-21, 29 and 31 are also not anticipated by Yamada et al. for at least the same reasons as claim 1.

In view of the above, withdrawal of the rejection is respectfully requested.

II. Response to Rejection of Claims 7-8, 11, 12, 16, 23-25, 27, 28, 32, and 33 Under 35 U.S.C. § 103

Claims 7-8, 11, 12, 16, 23-25, 27, 28, 32, and 33 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP '562, as evidenced by M. Schreiner, and further in view of Unger et al (USP 6,090,800).

Applicants respectfully traverse the rejection.

It is respectfully submitted that claims 7-8, 11, 12, 16, 23-25, 27, 28, 32, and 33 are patentable for at least the same reasons as claims 1 and 18, as discussed above. Specifically, independent claim 33 relates to a method for manufacturing a fat emulsion comprising a stabilizer (a), (b), (c), or (d). Accordingly, claim 33 is not taught or suggested by the cited references for at least the same reason as claim 1.

In addition, Unger et al. is cited as teaching the use of a wide variety of lipids as stabilizers for pharmaceutical compositions. The Examiner states that examples of lipids include distearoylphophatidylglycerol, palmitic acid, stearic acid, oleic acid, dioleylphosphatidylethanolamine, distearoylphosphatidylethanolamine-polyethylene glycol 5000, and the like.

However, Unger et al. discloses an extremely wide range of compounds as stabilizers in addition to the ones above. Further, Unger et al. does not disclose a specific fat emulsion comprising propofol, an oily component, and an emulsifier, as a pharmaceutical composition in which the stabilizers are effectively used. Therefore, regarding a specific fat emulsion comprising propofol, an oily component, and an emulsifier, Unger et al. does not teach a specific stabilizer able to satisfy the purpose that emulsion stability is not impaired when a local anesthetic is admixed.

Further, as discussed above, Yamada et al. discloses a fat emulsion comprising an O/W-type emulsion containing propofol and lidocaine, but it merely disclose a hydrophilic surfactant of 10 or more HLB as a stabilizer. Table 1 of Yamada et al. presenting the stability test results of some stabilizers does not include stabilizers (a) to (d) used in the present invention nor any compounds analogous thereto. Given this, even considering the description of Unger et al., one of ordinary skill in the art would not readily select or use stabilizers (a) to (d) of the present invention, which are completely different from the hydrophilic surfactants of 10 or more HLB

disclosed as stabilizers in Yamada et al., from the numerous stabilizers exemplified in Unger et al.

In sum, Yamada et al. merely teaches a hydrophilic surfactant of 10 or more HLB, which is a completely different from the stabilizers used in the present invention. Unger et al. teaches various lipids as stabilizers usable in pharmaceutical compositions, but not a specific stabilizer providing an effect by which emulsion stability is not impaired even when a local anaesthetic is mixed with a fat emulsion containing propofol, an oily component and an emulsifier. Thus, even if Yamada et al. and Unger et al. were somehow combined, one of ordinary skill in the art would not readily arrive at the present invention according to claims 7, 8, 11, 12, 16, 23 to 25, 27, 28 and 32, which require the use of a specific stabilizer.

In view of the above, withdrawal of the rejection is respectfully requested.

III. Response to Rejection of Claim 17 under 35 U.S.C. § 103(a)

Claim 17 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over JP '562 and further in view of Yugari (US 2001/0047162).

Applicants respectfully traverse the rejection.

The Examiner has indicated that Yugari teaches a container having a similar structure to this claimed container. However, in addition to the configuration of the container, claim 17 recites a fat emulsion comprising stabilizers (a) to (d). That is, one of the multi-compartments of the container contains the fat emulsion of claim 1. Since the fat emulsion of claim 1 is not disclosed, taught or suggested in Yamada et al., one of ordinary skill in the art would not readily arrive at the method of claim 17, even if Yamada et al. and Yugari were somehow combined.

In view of the above, withdrawal of the rejection is respectfully requested.

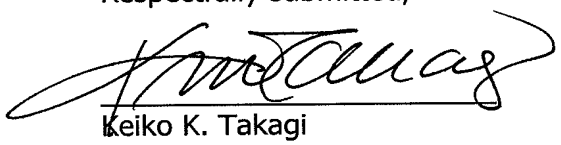
IV. Conclusion

For the foregoing reasons, reconsideration and allowance of claims 1-5, 7-9, 11-13, 15-21, 23-25, 27-29 and 31-33 is respectfully requested.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



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